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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,417	11/20/2003	Takeo Tanaami	032106	6545
38834	7590	02/07/2006		
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036				EXAMINER BOWERS, NATHAN ANDREW
				ART UNIT 1744 PAPER NUMBER

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,417	TANAAMI ET AL.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-25 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>112003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Objections***

Claims 1 and 2 are objected to because of the following informalities:

Claim 1 indicates that the flow paths and areas are formed *on* the substrate, whereas all subsequent depending claims indicate that the flow paths and areas are formed *in* the substrate without giving any indication that a change has been made. Claim 2 indicates that the flow paths and areas are formed *on* and *in* the substrate at the same time, which seems contradictory. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 1) Claims 1, 12/(1) and 13/(1) are rejected under 35 U.S.C. 102(e) as being anticipated by Schnipelsky (US 6645758).

Schnipelsky discloses a biochip cartridge comprising a tabular substrate member (Figure 2:12) formed using an elastic material, and a flexible cover (Figure 2:14) attached to the surface of the substrate in an airtight manner. This is disclosed in column 9, lines 33-49 and column 10, lines 45-53. An area

(Figure 1:32) for storing/collecting biopolymers, an area for preprocessing biopolymers (Figure 1:26) and an area (Figure 1:40) for detecting desired biopolymers are all formed on the substrate, so that the biopolymers can be successively moved from the storage area to the detection area through gaps (Figure 1:21, 43, 44, 48, 49, 50, 52) serving as flow paths. This is disclosed in column 9, line 50 to column 10, line 15.

With respect to claim 12(/1), Schnipelsky discloses the apparatus in claims 1 and 2, wherein a valve for checking the flow of solutions is provided in the flow path and the valve opens when a solution flowing through the flow path is pressurized. This is disclosed in column 10, lines 11-15.

With respect to claim 13(/1), Schnipelsky discloses the apparatus in claims 1 and 2, wherein the substrate member is formed using a plastic-deformable material. This is disclosed in column 9, lines 33-49 and column 10, lines 45-54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2) Claims 1-5, 7 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky (US 6645758) or Applicant's admitted prior art in view of Hayes (US 6334980).

With respect to claims 1 and 2, Schnipelsky discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejection above. Although Schnipelsky does not expressly state that the storage area (Figure 1:32) and the preprocessing area (Figure 1:26) are in series, they intrinsically could be so arranged if the immediate application required that biopolymers move from the storage area to the preprocessing area. This type of arrangement is well known in the art. Schnipelsky, however, discloses that the gaps and the storage, preprocessing and detecting areas are formed *on* the substrate and not *in* the substrate.

Applicant discloses that it is known in the art to prepare biochip cartridges comprising a tabular substrate member attached to a flexible cover in an airtight manner. The use of fluidly connected storage (Figure 5:43), preprocessing (Figure 5:44) and detection (Figure 5:45) areas is also known. This is taught on pages 3 and 4 of the specification. However, it is not disclosed that channels and chambers are formed into the substrate in order to construct the biochip cartridge. The disclosed prior art states that these features are formed on top of the substrate and not within the substrate.

Hayes discloses a biochip cartridge comprising an elastic and tabular substrate member (Figure 1:20) that includes preprocessing (Figure 1:40) and detection (Figure 1:60) areas formed directly into the substrate. The biochip is used to amplify nucleic acids in the preprocessing area and detect desired PCR products in the detection area. This is disclosed in column 4, lines 5-40. Hayes

teaches in column 6, lines 10-22 that a transparent cover is positioned over the substrate to seal the preprocessing and detection areas.

Schnipelsky, Applicant's disclosed prior art, and Hayes are analogous art because they are from the same field of endeavor regarding fluidic systems designed to process a biopolymer sample.

At the time of the invention, it would have been obvious to alter the prior art or Schnipelsky's invention in order to integrally form reaction chambers and flow channels within the disclosed substrates. This would involve making the substrates thicker, so that desired biochip cartridge components (chambers, gaps, etc) could be etched directly into the substrate material. This would have been an improvement over forming the chambers and channels in the area between the top of the substrate and the bottom of the cover because it would have decreased the complexity and increased the reproducibility of construction. Hayes teaches in column 4, lines 4-20 that chambers and channels cut into the substrate in this way may be created quickly, precisely, and in any desired arrangement. This would have been much easier than creating a plurality of "pouch-like" chambers from the cover as required by the Schnipelsky reference.

With respect to claims 3 and 7, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant's admitted prior art teaches on page 5 of the specification that fluid flow is induced by pressing the cover with a roller to move biopolymers from the collection area to the preprocessing area, and finally to the detection area. Schnipelsky discloses in column 10, lines 15-29

that a roller is used to compress the cover and squeeze each gap in a time differentiated manner.

With respect to claim 4, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant's admitted prior art teaches on pages 4 and 5 that pockets (Figure 5:48) are formed in the substrate member and are filled with a preprocessing solution. Schnipelsky states in that a plurality of pockets (Figure 1:30, 34, 36, 38) are formed and are emptied when pressed down upon by the roller.

With respect to claim 5, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. Applicant further discloses on page on page 4 of the specification that it is well known in the art to use a waste liquid reservoir (Figure 5:47) for storing drainage from the detection area. Schnipelsky also incorporates a waste area (Figure 1:42).

With respect to claim 10, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant's admitted prior art teaches on pages 4 and 5 that pockets (Figure 5:48, 50) for storing preprocessing solutions are formed in different positions so that when the substrate member is squeezed, a preprocessing solution is released in a time differentiated manner. Schnipelsky teaches that a plurality of pockets (Figure 1:30, 34, 36, 38) are formed, and are emptied when pressed down upon by the roller.

With respect to claim 11, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above. Although the above references do not disclose that the substrate is formed into a wedge shape, this embodiment of the invention would not change the function of the device in an unexpected manner. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was the recitation of relative dimensions that do not alter performance, the claimed device is not patentably distinct from the prior art. Accordingly, the claimed wedge shape is considered not to be patentably distinct from Applicant's admitted prior art or Schnipelsky when combined with Hayes.

With respect to claims 12 and 13, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claim 3 as set forth in the 35 U.S.C. 103 rejection above. In addition, Applicant teaches on page 5 that the use of a valve for checking the flow of solutions is well known in the art. Applicant states that the valve opens when a solution flowing through the flow path is pressurized. Furthermore, Schnipelsky discloses that the substrate member is formed using a plastic-deformable material. This is disclosed in column 9, lines 33-49 and column 10, lines 45-54.

- 3) Claims 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky (US 6645758) or Applicant's admitted prior art in

view of Hayes (US 6334980) as applied to claims 1 and 2, and further in view of Cohen (US 20020076354).

With respect to claim 6, the admitted prior art/Schnipelsky and Hayes disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the cover is attached to both the top and bottom surfaces of the substrate.

Cohen discloses a biochip cartridge (Figure 2:150) comprising a substrate (Figure 2:154) with a plurality of channels and chambers (Figure 2:164) formed therein. Transparent cover members (Figure 2:152, 156) are attached to both the top and the bottom to seal the features formed upon the substrate in an airtight manner. This is disclosed in paragraphs [0031]-[0042]. Paragraphs [0066] and [0067] indicate that the biochip cartridge is used for storing, processing, and detecting biopolymers.

Schnipelsky, Applicant's disclosed prior art, Hayes and Cohen are analogous art because they are from the same field of endeavor regarding fluidic systems designed to process a biopolymer sample.

At the time of the invention, it would have been obvious to seal both the top and bottom surfaces of the substrate disclosed by the admitted prior art/Schnipelsky and Hayes with cover members. This would have given one more flexibility in the construction of the biochip cartridge. In Cohen's invention, detection areas are formed within the substrate, however, the binding biochemicals (Figure 1:170) that are integral to the detection procedure are formed upon the bottom cover. This is beneficial because it would have allowed

one to attach multiple bottom covers containing probes with affinity to different biochemicals to the substrate. By doing so, one would be able to quickly and efficiently analyze a variety of different samples for the presence of a variety of different analytes.

With respect to claims 8 and 9, the admitted prior art/Schnipelsky, Hayes and Cohen disclose the apparatus set forth in claim 6 as set forth in the 35 U.S.C. 103 rejection above. Schnipelsky additionally discloses in column 10, lines 45-53 and column 13, lines 35-45 that the cover is transparent and is formed from plastics. The prior art additionally teaches that transparent cover materials are well known.

4) Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art in view of Hayes (US 6334980) as applied to claims 1 and 2, and further in view of Furcht (US 6303288).

With respect to claims 14-16, the admitted prior art and Hayes disclose the apparatus set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the biochip cartridge is made separable into a first housing and a second housing that are detachably joined.

Furcht discloses a genetic testing system comprising a test strip (Figure 1:11) that includes a first housing (Figure 3:32) and a test card (Figure 1:14) comprising a second chamber (Figure 2:63, 65). Column 8, line 34 to column 9, line 45 indicates that the first and second housings are detachably coupled, so that nucleic acid biopolymers stored and processed in the first chamber are

moved into the second chamber for detection. The second chamber comprises a joint (Figure 2:62) designed to facilitate attachment with the first chamber. In this way, biological samples can be added to the first housing and transferred to the second housing at different times. Column 11, lines 27-33 indicate that samples derived from the first chamber are amplified and detected in the second chamber through the use of PCR and hybridization to complementary biopolymer arrays.

Applicant's admitted prior art, Hayes, and Furcht are analogous art because they are from the same field of endeavor regarding the detection of biopolymers.

At the time of the invention, it would have been obvious to make the storage and detection areas of the apparatus disclosed by the prior art and Hayes detachable. This would have been beneficial because it would have allowed one to prepare a biological sample in a storage chamber under conditions that are different than experienced by the detection chamber. The two chambers could be combined to complete analysis at any convenient time. Many biochemical preparation procedures involve chemicals, enzymes or abnormal conditions (fluctuating temperatures and pHs, lysis enzymes, etc.) that are necessary to get a sample ready for analysis, but would be detrimental to the analytical procedures themselves. Therefore, one would be able to operate the biochip cartridge in a much more flexible and efficient manner if first and second housings comprising storage and detection areas were detachably separable.

With respect to claims 17 and 18, the admitted prior art, Hayes, and Furcht disclose the apparatus set forth in claims 14 and 16. In addition, Hayes teaches that it is common for substrates forming bioprocess chambers to be flexible. This is disclosed in column 3, lines 30-42 and throughout the reference. Hayes also teaches in column 6, lines 10-18 that transparent materials are well known in the art for the construction of hybridization areas in order to promote optical detection procedures. Applicant also teaches on page 3 of the specification that flexible and transparent materials are well known in the art.

5) Claims 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's admitted prior art in view of Hayes (US 6334980) as applied to claims 1 and 2, and further in view of McGarry (US 6642046).

With respect to claims 19 and 20, the admitted prior art and Hayes disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above. The prior art teaches that PCR is pursued in a preprocessing chamber as a mechanism to turn the biological samples into measurable biopolymers. The prior art also teaches that a microarray carrier (Figure 5:46) is mounted in the detection area. The prior art, however, does not expressly disclose that a carrier is a glass slide no greater than 25 mm wide and 75 mm long.

McGarry discloses a biochemical detection device in which biopolymer microarrays are mounted on a glass slide (Figure 2:20). The glass slide is mounted upon a substrate (Figure 1:32) in such a way that the microarrays

located on the glass slide are opposite the surface (Figure 1:34) of the substrate.

The glass slide and substrate form a reaction area (Figure 10:30) in which hybridization occurs. This is disclosed in column 5, line 51 to column 6, line 10. McGarry teaches in column 8, lines 23-39 that the dimensions of the glass slide are no greater than 25 mm wide by 75 mm long.

Schnipelsky, Hayes and McGarry are analogous art because they are from the same field of endeavor regarding biochemical detection devices.

At the time of the invention, it would have been obvious to fashion the microarray carrier disclosed by Schnipelsky from a 25 by 75 mm glass slide. This is due to the fact that glass is a rigid and inert substrate that is capable of covalently bonding to biochemical probes. Glass is relatively inexpensive and easily attained. The use of glass to accommodate the reactive surface of hybridization reaction chambers is well known in the art. Minimizing the size of the glass slide would also have been advantageous because it would have allowed one to reduce the volume of the hybridization detection area. This would have reduced the amount of sample needed to conduct the experiment, and would have reduced costs associated with the purchase of reagents.

With respect to claims 21, the admitted prior art, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art discloses that a collection area (Figure 5:43) for storing biological samples, a preprocessing solution storage area (Figure 5:44) for storing preprocessing solutions, a plurality of washing solution

storage areas (Figure 5:48, 50), a combination/detection area (Figure 5:45) for performing hybridization reactions, and a waste liquid reservoir (Figure 5:47) are all provided for within the biochip cartridge. This is disclosed in column 9, line 33 to column 10, line 15. A flow path connecting all the areas and storages in series is provided.

With respect to claim 22, the admitted prior art, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art discloses that the biological samples are transferred by squeezing the substrate member with a rigid roller (Figure 6:41) in the direction from the collection area toward the combination area. This is disclosed on page 5 of Applicant's specificaiton.

With respect to claims 23 and 24, the prior art, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. Furthermore, McGarry teaches that the glass slide biopolymer microarray (Figure 1:20) is mounted on the substrate member (Figure 1:32) in such a manner that the array area of the glass slide is opposed to the combination area (Figure 6:30). Additionally, a cover (Figure 1:54) formed of rigid material is attached to the substrate so that a cavity is formed therebetween.

At the time of the invention, it would have been obvious to form the hybridization/combination area disclosed by the prior art and Hayes from a glass slide microarray supported by a rigid cover and positioned oppositely from the

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substrate. This would have been beneficial because it would have created a sturdy reaction chamber within which hybridization can be monitored. The rigid cover member would have been able to provide a backing to the glass slide microarray, upon which pressure could be transmitted to force the glass slide into an airtight seal with the substrate. The subsequently formed hybridization and combination area can be constructed to be microfluidic in size, which would decrease expenses associated with the purchase of reagents.

With respect to claim 25, the prior art, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, the prior art teaches on pages 3 and 4 of Applicant's specification that DNA and RNA extraction mechanisms are well known, and are practiced during preprocessing operations.

6) Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnipelsky (US 6645758) in view of Hayes (US 6334980) as applied to claims 1 and 2, and further in view of McGarry (US 6642046).

With respect to claims 19 and 20, Schnipelsky and Hayes disclose the apparatus set forth in claims 1 and 2 as set forth in the 35 U.S.C. 103 rejection above. Schnipelsky teaches that PCR is pursued in a preprocessing chamber as a mechanism to turn the biological samples into measurable biopolymers. Schnipelsky also teaches that a microarray carrier (Figure 3:41) is mounted in

the detection area. Schnipelsky, however, does not expressly disclose that a carrier is a glass slide no greater than 25 mm wide and 75 mm long.

McGarry discloses a biochemical detection device in which biopolymer microarrays are mounted on a glass slide (Figure 2:20). The glass slide is mounted upon a substrate (Figure 1:32) in such a way that the microarrays located on the glass slide are opposite the surface (Figure 1:34) of the substrate. The glass slide and substrate form a reaction area (Figure 10:30) in which hybridization occurs. This is disclosed in column 5, line 51 to column 6, line 10. McGarry teaches in column 8, lines 23-39 that the dimensions of the glass slide are no greater than 25 mm wide by 75 mm long.

Schnipelsky, Hayes and McGarry are analogous art because they are from the same field of endeavor regarding biochemical detection devices.

At the time of the invention, it would have been obvious to fashion the microarray carrier disclosed by Schnipelsky from a 25 by 75 mm glass slide. This is due to the fact that glass is a rigid and inert substrate that is capable of covalently bonding to biochemical probes. Glass is relatively inexpensive and easily attained. The use of glass to accommodate the reactive surface of hybridization reaction chambers is well known in the art. Minimizing the size of the glass slide would also have been advantageous because it would have allowed one to reduce the volume of the hybridization detection area. This would have reduced the amount of sample needed to conduct the experiment, and would have reduced costs associated with the purchase of reagents.

With respect to claims 21, Schnipelsky, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, Schnipelsky discloses that a collection area (Figure 1:32) for storing biological samples, a preprocessing solution storage area (Figure 1:26) for storing preprocessing solutions, a plurality of washing solution storage areas (Figure 1:30, 34, 36, 38), a combination/detection area (Figure 1:40) for performing hybridization reactions, and a waste liquid reservoir (Figure 1:42) are all provided for within the biochip cartridge. This is disclosed in column 9, line 33 to column 10, line 15. A plurality of flow paths (Figure 1:21, 44, 48, 49, 50, 43) are also provided for connecting all the areas and storages. Although Schnipelsky does not expressly state that the storage area and the preprocessing area are in series, they intrinsically could be so arranged if the immediate application required that biopolymers move from directly from the storage area to the preprocessing area. This type of arrangement is well known in the art.

With respect to claim 22, Schnipelsky, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, Schnipelsky discloses that the biological samples are transferred by squeezing the substrate member with a rigid roller (Figure 1:60) in the direction from the collection area toward the combination area. This is disclosed in column 10, lines 15-29.

With respect to claims 23 and 24, Schnipelsky, Hayes and McGarry disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. Furthermore, McGarry teaches that the glass slide biopolymer microarray (Figure 1:20) is mounted on the substrate member (Figure 1:32) in such a manner that the array area of the glass slide is opposed to the combination area (Figure 6:30). Additionally, a cover (Figure 1:54) formed of rigid material is attached to the substrate so that a cavity is formed therebetween.

At the time of the invention, it would have been obvious to form the hybridization/combination area disclosed by Schnipelsky and Hayes from a glass slide microarray supported by a rigid cover and positioned oppositely from the substrate. This would have been beneficial because it would have created a sturdy reaction chamber within which hybridization can be monitored. The rigid cover member would have been able to provide a backing to the glass slide microarray, upon which pressure could be transmitted to force the glass slide into an airtight seal with the substrate. The subsequently formed hybridization and combination area can be constructed to be microfluidic in size, which would decrease expenses associated with the purchase of reagents.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Anderson (US 20050202504) and Zanzucchi (US 5858804) references teach the state of the art regarding biochip cartridges comprising storage, preprocessing, and detection areas formed in a substrate.

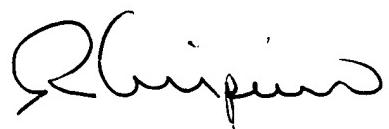
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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RICHARD CRISPINO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700